K131184

510(k) Summary

807.92(a)(1) – Submitter Information	
Name	Integra LifeSciences Corporation
Address	22 Terry Avenue Burlington, MA 01830
Phone Number	(781) 565-1347
Fax Number	(781) 238-0645
Establishment Registration Number	1222895
Name of Contact Person	Elizabeth McMeniman
Date Prepared	April 26, 2013
807.92(a)(2) – Name of device	
Trade or Propriety Name	Integra® Licox® PtO_2 Monitor
Common or Usual Name	Intracranial pressure monitor
Classification Name	Intracranial pressure monitoring device
Classification Panel	Neurology
Regulation	Class II, under 21 CFR 882.1620
Product Code(s)	GWM
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
• LICOX Brain Oxygen Monitoring System, CMP® Monitor and IMC® Systems – K002765 • LICOX PMO BRAIN MONITORING SYSTEM- K040235 • INTEGRA CAMINO ICP MONITOR- K121573 • INTEGRA CAMINO FLEX VENTRICULAR INTRACRANIAL PRESSURE MONITORING KIT WITH INTRGRA CAMINO FLEX ADAPTER- K121159	
807.92(a)(4) - Device description	
The Integra® Licox® PtO_2 monitor instrument is a diagnostic tool for continuously monitoring oxygen partial pressure (PtO_2) in - brain tissue. Minimally invasive probes are implanted directly into the brain tissue and are connected to the Licox monitor. The Integra Licox PtO_2 Monitor displays both PtO_2 and temperature in numeric format. The monitor will store PtO_2 trend data from the most recent 5 days. The user can elect to extract the trend data stored on the monitor to an external memory device or stream the data to a compatible PC via the USB output. The device also provides analog output for display on compatible bedside monitors.	
807.92(a)(5) – Intended Use of the device	
Indications for Use AUG 30 2013	The Integra Licox PtO_2 monitor measures oxygen partial pressure (PtO2) and temperature in brain tissue and these parameters are used together as an aid in the determination of the perfusion status of cerebral tissue local to sensor placement. Monitor values are relative within an individual, and should not be used as the sole basis for determining a diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Intended Users	The operation of the Licox PtO_2 monitor is to be performed by designated qualified hospital staff (i.e. neurosurgeon, nurse, intensivist, trauma physician, physician's assistant, or other appropriately trained staff).

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The design of both the modified device and the predicate device are similar. Both of the devices receive signals from the probes that are then translated into the oxygen partial pressure & temperature readings. These readings are then displayed on the screen for the health care practitioners to use as additional information in treatment of the patient.

Integra Licox PtO_2 monitor and the predicate device have the same intended uses, environment for use, device classifications, product codes and measureable parameters as outlined in the substantial equivalence chart and discussion. Any differences in the technological characteristics of the new device do not raise different questions of safety and effectiveness than the predicate device. .

Product Characteristics	**Comparison Integra® Licox® PtO_2 Monitor to the predicate LICOX Brain Oxygen Monitoring System, CMP® Monitor**
Parameter Display	
PtO2 Trend (5 day) Display	The predicate Licox CMP Monitoring System does not trend PtO2 data.
Trend Data Storage	The predicate Licox CMP Monitoring System does not trend or store PtO2 data.
Trend Data Retention	The predicate Licox CMP Monitoring System does not retain data specific to the probe.
Data Output	The predicate Licox CMP Monitoring System does not include a USB port.
System PtO_2 Performance Requirements	Same
Alarms	The predicate Licox CMP Monitoring System does not have a Low PtO2 Alarm or a Low Battery Alarm
Parameter Indicators	Same
User Inputs via GUI screen	The predicate Licox CMP Monitor used a key pad.
Portability and Handling	The predicate Licox CMP Monitor cannot be mounted to a pole. The proposed Licox PtO2 monitor can be mounted to a pole with diameter between 0.5 and 1.2 inches outer diameter.
Bedside Output	Same

807.92(b)(1-2) – Nonclinical Tests Submitted

The Integra Licox PtO2 monitor was tested in accordance with the relevant test plans/reports included with this 510(k) submission using the production equivalent units.

Testing was performed to ensure that the device met pre-defined performance and safety specifications and to ensure that hazard mitigations functioned as designed.

Testing includes, but is not limited to the following:

- PtO_2 Accuracy
- Temperature Accuracy
- Alarm setting, accuracy, volume etc.
- Trend functionality
- Data Export Functionality (bedside monitor, external storage)
- Fault testing
- Electromagnetic Compatibility
- Electrical Safety
- Environmental Testing
- Cleaning Testing

807.92(b)(3) – Conclusions drawn from non-clinical data

All necessary testing has been completed for the Integra Licox PtO_2 monitor and the test results support the conclusion that all Design Inputs (requirements and specifications) have been met. Testing confirmed that the Integra Licox PtO_2 monitor is safe and effective under the proposed conditions of use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

Integra LifeSciences Corporation
% Ms. Elizabeth McMeniman
Senior Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K131184
Trade/Device Name: Integra® Licox® PtO_2 Monitor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: July 26, 2013
Received: July 29, 2013

Dear Ms. McMeniman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131184

Device Name: Integra® Licox® PtO_2 Monitor

Indications For Use:

The Integra Licox PtO_2 Monitor measures oxygen partial pressure (PtO_2) and temperature in brain tissue and these parameters are used together as an aid in the determination of the perfusion status of cerebral tissue local to sensor placement. Monitor values are relative within an individual, and should not be used as the sole basis for determining a diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice in cases where hypoxia or ischemia are a concern.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K131184